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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,913	08/21/2003	Michael M. Grunstein	T1118/20102	9590

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CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOW, LTD.  
11TH FLOOR, SEVEN PENN CENTER  
1635 MARKET STREET  
PHILADELPHIA, PA 19103-2212

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/645,913

Applicant(s)

GRUNSTEIN ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1,2, 3-26, and 38-43, drawn to methods of treating asthma in humans by administering proteins, polypeptides or antibodies that inhibit the binding of IgE to FcεRII, classified in class 424, subclass 143.1.
  - II. Claims 1, 2, 7-15, 20-26, and 38-43, drawn to methods of treating asthma in humans by administering synthetic peptides that inhibit the binding of IgE to FcεRII, classified in class 514, subclass 2.
  - III. Claims 1, 2, 7-15, 20-26, and 38-43, drawn to methods of treating asthma in humans by administering non-peptides that inhibit the binding of IgE to FcεRII, classified in class 514, subclass 1.
  - IV. Claims 27 and 28, drawn to screening methods that identify agents that inhibit the binding of IgE to FcεRII, classified in class 435, subclass 7.1.
  - V. Claim 29, drawn to an agent identified by a screening assay, classified in class 530, subclass 350.

- VI. Claim 30, drawn to a method of inhibiting binding of IgE to a cell by contacting a cell with a protein, polypeptide or antibody, classified in class 435, subclass 7.2.
- VII. Claim 30, drawn to a method of inhibiting binding of IgE to a cell by contacting a cell with a synthetic peptide, classified in class 435, subclass 7.8.
- VIII. Claim 30, drawn to a method of inhibiting binding of IgE to a cell by contacting a cell with a non-peptide, classified in class 435, subclass 4.
- IX. Claim 31, drawn to a method of regulating interleukin 1 $\beta$  in vitro by administering a protein, polypeptide or antibody that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 530, subclass 387.1.
- X. Claim 31, drawn to a method of regulating interleukin 1 $\beta$  in vitro by administering a synthetic peptide that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 350, subclass 300.
- XI. Claim 31, drawn to a method of regulating interleukin 1 $\beta$  in vitro by administering a non-peptide that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 530, subclass 868.

XII. Claims 31-37, drawn to methods of regulating interleukin  $1\beta$  in a human by administering a protein, polypeptide or antibody that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 424, subclass 145.1.

XIII. Claims 31-37, drawn to methods of regulating interleukin  $1\beta$  in a human by administering a synthetic peptide that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 514, subclass 8.

XIV. Claims 31-37, drawn to methods of regulating interleukin  $1\beta$  in a human by administering a non-peptide that inhibits the binding of IgE to Fc $\epsilon$ RII, classified in class 424, subclass 184.1.

2. Claims 1, 2, 14, and 15 link Inventions I-III. Claim 30 links inventions VI-VIII. Claim 31 links inventions IX-XIV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claims, claims 1, 2, 14, and 15 for Groups I-III, 30 for Groups VI-VIII, and 31 for Groups IX-XIV. Upon the indication of allowability of the linking claims, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise requiring all the limitations of the allowable linking claims will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is

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presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant is advised that if any claims including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions IV and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case agents capable of inhibiting binding of IgE to FcεRII can be made by methods other than those recited in the claims, such as injecting an animal with soluble CD23 and harvesting the resulting antibodies.

4. Inventions V and (I-III, VI-XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the agent used to inhibit binding of IgE to FcεRII can also be used in methods of purifying FcεRII and can also be used as positive control in methods that identify additional agents that block the interaction of IgE and FcεRII.

5. Inventions I-IV and VI-XIV are different methods. As such they recite different process steps such as administering, contacting, and identifying, require unique ingredients such as polypeptides, antibodies, synthetic peptides, and non-peptides, and achieve divergent of treating asthma, identifying agents, inhibiting IgE binding to FcεRII, and regulating production of interleukin 1β. Art that anticipates or renders obvious one group would not necessarily anticipate nor render obvious the invention of the other group. The patient population in which one would want to regulate interleukin 1β production is potentially distinct from asthmatic patients, and methods that are performed in vitro may not be directly translated in to in vivo therapeutic methods. Therefore they are patentably distinct. The agents used in such treatment methods are quite divergent in their structure and potential mechanism of action, such as binding to IgE to limit its interaction with FcεRII, binding directly to FcεRII to block interactions, or

decreasing the transcription and ultimate translation of FcεRII on the surface of a cell.

For all of these reasons the methods are patentably distinct.

6. Because these inventions are distinct for the reasons given above, because the literature searches required for Groups I-XIV are not coextensive in that art that anticipates or renders obvious the invention of any one group would not necessarily anticipate or render obvious the inventions of the other groups, and because Groups I-XIV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to the following patentably distinct species of Groups I-III. These species are the route of administration that is used to administer the agent that inhibits binding of IgE to FcεRII. The species are independent or distinct because the route of administration can influence the effectiveness of therapeutic method and may limit the identity of the administered agent since applicant's claimed therapeutic agents may not be amenable to administration via all delivery methodologies. In response to this action, applicant is required to elect parenteral, topical, oral (digestive system) or inhalation (respiratory system) as a method of administration.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is

finally held to be allowable. Currently, claims 1-6, 11, 12, 14-19, 24, and 25 of Group I and claims 1-3, 11, 12, 14, 15, 24 and 25 of Groups II and III generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.  
MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.  
Patent Examiner  
Technology Center 1600  
April 13, 2006

  
Patrick J. Nolan, Ph.D.  
Primary Examiner  
Technology Center 1600  
4/14/06